

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

CIVIL ACTION NO. 99-20593

v.

AMERICAN HOME PRODUCTS
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8661

Bartle, J.

August 8, 2011

Hazel J. Morehouse ("Ms. Morehouse" or "claimant"), a class member under the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2003,³ claimant submitted a completed Green Form to the Trust signed by her attesting physician, Thomas B. Pinto, M.D., F.A.C.C. Based on an echocardiogram dated March 23, 2000, Dr. Pinto attested in Part II of Ms. Morehouse's Green Form that she suffered from moderate aortic regurgitation⁴

2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. According to the Trust, claimant submitted a Green Form in January, 2002. The Show Cause Record does not contain a Green Form reflecting that submission.

4. Dr. Pinto also attested that claimant suffered from mild mitral regurgitation, moderate mitral regurgitation, mitral annular calcification, pulmonary hypertension secondary to severe aortic regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial
(continued...)

and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. Based on such findings, claimant would be entitled to Matrix A-1, Level III⁵ benefits in the amount of \$619,999.⁶

In the report of claimant's March 23, 2000 echocardiogram, the reviewing cardiologist, David M. Murello, M.D., noted that "[t]he aortic cusps are somewhat thickened and calcified but open normally." Dr. Pinto, however, attested in claimant's Green Form that Ms. Morehouse did not suffer from aortic sclerosis. Under the Settlement Agreement, the presence of aortic sclerosis in Diet Drug Recipients who were sixty (60) years of age or older at the time they were first diagnosed as FDA Positive⁷ requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). As

4. (...continued)
dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class III symptoms. These conditions, however, are not at issue in this claim.

5. In Part I of her Green Form, Ms. Morehouse requested Matrix Benefits at Level IV. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant did not contest, that Ms. Morehouse only alleged conditions consistent with a claim for Level III benefits.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

7. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve...." Settlement Agreement § I.22.a.

the Trust does not contest Ms. Morehouse's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In April, 2004, the Trust forwarded the claim for review by Christopher M. Kramer, M.D., F.A.C.C., F.A.H.A, one of its auditing cardiologists. In audit, Dr. Kramer concluded that there was a reasonable medical basis for Dr. Pinto's findings that claimant had aortic regurgitation and surgery to repair or replace the aortic valve. Dr. Kramer did not find that Ms. Morehouse suffered from aortic sclerosis.

By letter dated July 8, 2004, the Trust advised claimant that her claim was potentially payable on Matrix A and requested medical records pursuant to Court Approved Procedure ("CAP") No. 4, as adopted in Pretrial Order ("PTO") No. 2805 (Mar. 26, 2003). By letter dated January 13, 2005, the Trust issued a post-audit determination, which advised claimant that, because she had failed to comply with PTO No. 2805, her claim would be paid on Matrix B-1. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸ In contest, claimant challenged the auditing cardiologist's finding that the level of Ms. Morehouse's

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Morehouse's claim.

aortic regurgitation was only moderate. In support, claimant relied on the report of a February 26, 1999 echocardiogram, which stated, "Aortic valve sclerosis with severe aortic insufficiency increased from moderate prior exam of 09/97." In addition, Ms. Morehouse argued that her current heart condition was caused by her ingestion of Diet Drugs.⁹

Based on claimant's additional submissions, the Trust forwarded the claim to an additional auditing cardiologist, Craig M. Oliner, M.D., for a second review. In audit, Dr. Oliner concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have aortic sclerosis. In support, Dr. Oliner stated that:

Although the 3/23/00 [echocardiogram] parasternal views are of suboptimal quality and therefore the [echocardiogram] is not definitive, the pathology report from surgery describes "degenerative changes" and "nodular and slightly thickened" [aortic valve] leaflets. At surgery, the [aortic valve] is described as "myxomatous appearing." These findings are diagnostic of aortic sclerosis.

The Trust then issued a final post-audit determination, again determining that Ms. Morehouse was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c).

9. Claimant also argued that the attesting physician's determination with respect to mitral annular calcification was erroneous. As Ms. Morehouse's claim is based on damage to her aortic valve, we need not address this issue.

The Trust then applied to the court for issuance of an Order to show cause why Ms. Morehouse's claim should be paid. On December 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6812 (Dec. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 25, 2007 and claimant submitted a sur-reply on November 20, 2007. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she did not have aortic sclerosis at the time she was first diagnosed as FDA Positive. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Morehouse argues that the Trust cannot rely on the reports of her September 12, 1997 and February 26, 1999 echocardiograms because they were prepared by claimant's treating physician and not a "Qualified Physician" as required by the Settlement Agreement.¹⁰ In addition, claimant asserts that the Trust's first auditing cardiologist did not find that claimant had aortic sclerosis on the echocardiogram of attestation and therefore the second auditing cardiologist's opinion should not be relied upon to reduce the amount of claimant's Matrix Benefits. In addition, claimant submits a letter from Arnold B. Meshkov, M.D., who reviewed claimant's April 28, 1999 and March 23, 2000 echocardiograms and according to claimant concluded that aortic sclerosis was not present on either echocardiogram. Finally, claimant also argues that Dr. Oliner did not rely on new medical information in finding that claimant suffered from aortic sclerosis.

In response, the Trust argues that it properly relied on Dr. Oliner's opinion because, in contest, claimant produced additional medical records that were not available to the initial auditing cardiologist, Dr. Kramer. The Trust also asserts that the opinion of claimant's expert does not assist claimant in establishing that she does not have aortic sclerosis because he did not state that claimant did not have aortic sclerosis but

10. The Settlement Agreement defines a "Qualified Physician" as "a Board-Certified or Board-Eligible Cardiologist." Settlement Agreement § I.47.

only that the April 28, 1999 echocardiogram is "less than optimal from a technical standpoint" and that the March 23, 2000 echocardiogram demonstrates a "slight thickening of the aortic valve leaflets." Finally, to address claimant's argument that Dr. Oliner purportedly did not review the entirety of the claim file, the Trust submitted a declaration from Dr. Oliner, which states, in relevant part, that:

6. Upon review of the Claim, I stated that Claimant's medical records clearly documented the presence of aortic sclerosis and that there is no reasonable medical basis for the Attesting Physician's finding to the contrary. My finding of aortic sclerosis was based upon review of Claimant's entire claim file. While her March 23, 2000 echocardiogram tape was suboptimal for forming a diagnosis as to the presence or absence of aortic sclerosis, Claimant's medical records, including the contemporaneous reports of echocardiogram studies performed on September 12, 1997 and February 26, 1999 were unequivocal as to the presence of aortic sclerosis.
7. In light of Claimant's Show Cause Response, I was contacted by the Trust and asked to review this Claim again, including Claimant's March 23, 2000 [echocardiogram] study. For the first time, I was also provided with an echocardiogram disk dated April 28, 1998, which was submitted with Claimant's Response. The Trust has represented to me that the disk containing the April 28, 1998 study is the actual disk provided by Claimant in her Response, and is not a copy.
8. In accordance with the Trust's request, I again reviewed the entirety of Claimant's March 23, 2000 echocardiogram tape, as well as Claimant's medical

records, including the April 28, 1998 echocardiogram.

9. Based on my review, I confirm my finding that there is no reasonable medical basis for the Attesting Physician's finding that Claimant does not have aortic sclerosis based on the studies and records available. I have reviewed the April 28, 1998 echocardiogram. However, due to a low gain setting, the images are very dark, rendering it impossible to evaluate the presence or absence of aortic sclerosis based upon review of this [echocardiogram]. It is difficult to visualize the aortic leaflets, much less determine whether or not aortic sclerosis is present. Accordingly, it is impossible for me to rule out the presence of aortic sclerosis based upon review of this echocardiogram. There is no reasonable basis for concluding that findings as to aortic sclerosis observed and reported on the studies of September 12, 1997 and February 26, 1999 were erroneous based on the April 28, 1998 study provided with Claimant's Response materials.
10. As in my initial evaluation of this Claim, I have based my finding of aortic sclerosis upon Claimant's medical records, including echocardiogram reports dated September 12, 1997 and February 26, 1999, along with the Surgical Pathology and Operative reports of April 16, 2001. Specifically, the September 12, 1997 and February 26, 1999 echocardiogram reports, which are roughly contemporaneous with the April 28, 1998 echocardiogram, report the presence of aortic sclerosis.
11. I have also reviewed Claimant's March 23, 2000 echocardiogram again. As with my initial review, I found that the views necessary to determine the presence or absence of aortic sclerosis are of suboptimal quality. Accordingly, it is not possible to definitively state

whether or not aortic sclerosis is present on this [echocardiogram].

12. Accordingly, I affirm my finding that Claimant's medical records demonstrate the presence of aortic sclerosis, and that there is no reasonable medical basis for the Attesting Physician's representation on the Green Form that Claimant does not have aortic sclerosis.

In her sur-reply, Ms. Morehouse argues that the Trust did not follow the reasonable medical basis standard because it relied solely on the opinion of Dr. Oliner and ignored the conclusions of the initial auditing cardiologist, claimant's attesting physician, and claimant's expert. Ms. Morehouse also asserts that a February 8, 2001 echocardiogram establishes that she did not have aortic sclerosis. Finally, Ms. Morehouse again asserts that the echocardiogram reports prepared by her treating physician cannot be used to determine the presence of aortic sclerosis because her attesting physician is not a "Qualified Physician" as defined by the Settlement Agreement.

After reviewing the entire show cause record, we find claimant's arguments are without merit. The Settlement Agreement specifically provides that the presence of aortic sclerosis in Diet Drug Recipients who were sixty (60) years of age or older at the time they were first diagnosed as FDA Positive requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). There is no dispute that Ms. Morehouse was first diagnosed as FDA Positive after reaching age sixty (60). The Show Cause Record also contains two (2) echocardiogram

reports provided by claimant in contest, each of which specifically states that claimant had aortic sclerosis. The report of claimant's September 12, 1997 echocardiogram, prepared by Kamlesh B. Gosai, M.D., MPH, states that claimant had "[a]ortic valve sclerosis with moderate aortic insufficiency." Similarly, the report of claimant's February 26, 1999 echocardiogram, also prepared by Dr. Gosai, states that claimant had "[a]ortic valve sclerosis with severe aortic insufficiency increased from moderate in prior exam of 09/97."¹¹

In addition, despite the opportunity, claimant does not adequately challenge the specific findings of the second auditing cardiologist, Dr. Oliner, that claimant's medical records contained findings consistent with a diagnosis of aortic sclerosis. Instead, claimant relies on the opinion of her expert, Dr. Meshkov. His opinion, however, is of no assistance to claimant because he does not specifically conclude that claimant did not have aortic sclerosis. Nor does Dr. Meshkov dispute Dr. Oliner's conclusion that the findings in claimant's pathology and operative reports are consistent with a diagnosis of aortic sclerosis. Dr. Meshkov also does not address the

11. We reject claimant's assertion that the court should not consider these reports because they were prepared by claimant's treating physician who is not a "Qualified Physician" as defined by the Settlement Agreement. First, nothing in the Settlement Agreement requires that a Qualified Physician determine the existence of the reduction factor of aortic sclerosis. Second, neither claimant's attesting physician nor claimant's expert reviewed these echocardiogram reports and accompanying screenshots and opined that the conclusions of claimant's treating physician as to aortic sclerosis were erroneous.

September 12, 1997 and February 26, 1999 echocardiogram reports (and supporting still frames), in which claimant's treating physician concluded that Ms. Morehouse had aortic sclerosis.¹²

We also disagree with claimant that the conclusions of Dr. Oliner, which were based on a second review of Ms. Morehouse's claim, should be disregarded. As discussed above, claimant's own medical records reveal that she had the reduction factor of aortic sclerosis. Moreover, Ms. Morehouse provided additional medical records pursuant to CAP No. 4, which is designed to determine whether a claim is payable on Matrix A or Matrix B. Thus, the Trust acted properly in having the claim, with the additional medical records, reviewed a second time, and we will not disregard the conclusions of the Trust's additional auditing cardiologist.

Finally, the court rejects Ms. Morehouse's assertion that she is entitled to Matrix A-1 benefits because she did not have a preexisting heart condition until after her ingestion of Diet Drugs. Causation is not at issue in resolving Ms. Morehouse claim for Matrix Benefits. Rather, Ms. Morehouse is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the

12. For these reasons as well, we reject claimant's assertion that the Trust did not properly apply the reasonable medical basis standard.

Matrices represent an objective system of compensation whereby claimants need only provide that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation at issue. The Settlement Agreement unequivocally requires a claim to be reduced to Matrix B-1 if the claimant suffered from aortic sclerosis and was sixty (60) years of age or older at the time he or she was first diagnosed as FDA Positive. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). We must apply the Settlement Agreement as written. Accordingly, claimant's argument that she did not have a heart condition prior to Diet Drug use, even if true, is irrelevant.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have aortic sclerosis at the time she was first diagnosed as FDA Positive. Therefore, we will affirm the Trust's denial of Ms. Morehouse's claim for Matrix A-1 Benefits.